

Indiana Board of Pharmacy

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Governor Michael R. Pence

Executive Director Virgil R. Madden

Nora Apothecary, Inc., located at 1101 East 86th Street, Indianapolis, IN 46240, has informed the Indiana Board of Pharmacy and the Food and Drug Administration that they have initiated a voluntary recall of compounded products within their expiration date that were compounded and dispensed by the pharmacy on or before Friday, April 19, 2013.

The Indiana Board of Pharmacy has been working closely with the FDA in an effort to ensure that Hoosiers receive safe and effective compounded medications. A Board of Pharmacy inspector observed violations during an FDA-led inspection. After the FDA inspection, the Board of Pharmacy had the pharmacy cease all sterile compounding activities until they remedied their deficiencies. The inspector advised the use of an isolator to help achieve and maintain compliance with the Indiana Board of Pharmacy's USP 797-based standards. Since then, the inspector has verified the installation and certification of an isolator. Unannounced follow up inspections will continue to be conducted.

The Indiana Board of Pharmacy has referred the matter to the Indiana Attorney General's Office to investigate whether or not there have been any federal violations that warrant license discipline.

The Board of Pharmacy continues to monitor all pharmacy activities, including compounding, in an effort to protect public safety. The Indiana Professional Licensing Agency takes patient safety very seriously, and we continue to be vigilant in protecting all 6.5 million Hoosiers.

For recall information please contact Nora Apothecary at (317) 251-9547 or 800-729-0276 or by email at pharmacist@noraapothecary.com. Adverse reactions or quality problems experienced with the use of any Nora Apothecary products may be reported to the FDA's MedWatch Adverse Event Reporting program at www.fda.gov/medwatch/report.htm.